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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/993,393	11/23/2001	George Jackowski	2132.110	4947
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EXAMINER

COOK, LISA V

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/993,393	Applicant(s) JACKOWSKI ET AL.	
	Examiner Lisa V. Cook	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 May 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) 39-46 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1 and 39-46 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Art Unit: 1641

DETAILED ACTION

Amendment Entry

1. Applicants response filed May 9, 2005 is acknowledged. In the amendment filed therein, claims 1, 39 and 44-46 were modified. Claims 2-38 have been canceled without prejudice or disclaimer.

Claim Status

2. Claims 39-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10 December 2004.

3. Currently claim 1 is under consideration.

4. Rejections and/or objections of record not reiterated herein have been withdrawn.

OBJECTIONS WITHDRAWN

Information Disclosure Statement

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.

Art Unit: 1641

6. The information disclosure statements filed 4/2/02, 5/16/03, and 10/20/03 have been considered as to the merits prior to first action.

Response to Arguments

Applicant contends that the references cited within the specification but not included in the IDS were merely provided for general information and are not deemed pertinent to the patentability of the claimed invention. Accordingly the objection of the IDS is withdrawn.

Specification

7. The use of the trademarks has been noted in this application. (i.e. SEPHAROSE on page 41 lines 2 and 3, TRITON on page 42 line 10, and TRITON on page 43 line 2). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Abstract

8. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Art Unit: 1641

9. The instant application includes legal phraseology "said". Appropriate correction is required.

Response to Arguments

Applicants have corrected all the items listed in numbers 7, 8, and 9 above via amendment. Therefore the objections are withdrawn.

NEW GROUNDS OF REJECTIONS NECESSITATED BY AMENDMENT

Please Note: Although the rejections below were slightly modified to address the newly amended claims. There is no "new ground" of rejection when the "basic thrust" of the rejection is the same. Ex parte Maas, 9 USPQ.2d 1746 (Bd. Pat. App. & Int. 1987).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, credible or asserted utility or a well-established utility.

Claim 1 is drawn to a biopolymer marker consisting of SEQ ID NO:4. The specification discloses that the utility of the diagnostic marker is in its association or link to Type II diabetes. The disclose further postulates that the biopolymer marker is useful in methods determining the differential regulation of SEQ ID NO:4; wherein the differential expression (presence/absence/down regulation) of the sequence indicates a link or associations with Type II diabetes.

Art Unit: 1641

These specification also discloses diagnostic methods employing the biopolymer in evidencing, characterization, regulation, risk-assessment, and therapeutic identification. The specification contemplates the use of these methods for diagnosing, staging, monitoring, prognosticating or determining conditions associated with Type II diabetes.

Applicants have disclosed in the specification that SEQ ID NO: 4 is differentially expressed in normal patients (figure 1 lanes 2-6) in comparison to Type II diabetes patients (figure 1 lanes 7-10). See page 46 line 8 through page 47 line 1. However, figure 1 appears to show the expression of SEQ ID NO:4 in normal patients as well as Type II diabetes patients (See figure 1 lanes 2-10). No clear difference in up and down regulation of the marker can be determined. Therefore, SEQ ID NO:4 does not appear to be associated/linked to/marker for Type II diabetes (clearly differentiating/distinguishing the disease from control/normal patients). See Band 3 in figure 1.

Figure 1 does not conclusively set forth the utility of the specification (association/link to Type II diabetes). For example, page 46 lines 6-22 of the specification discloses that several markers are differentially associated with Type II diabetes but a clear conclusion with respect to marker differentiation is not set forth in the specification or the figures. Without any clear differentiation or means for determining such differentiation the determination of a candidate marker for subsequent evaluation would require undue experimentation.

Applicant contends that fragments of apolipoprotein A-IV precursor expressed in Band 3 of figure 1 exemplifies differential expression in control/normal samples when compared to Type II diabetes samples (see specification page 46 lines 6-22), however; in figure 1 Band 3 is not differentially expressed. In fact, Band 3 appears to be expressed similarly in all the lanes.

Art Unit: 1641

Therefore, it is deemed that the disclosure teaches inconclusive results and one of skill in the art would not be convinced that fragments consisting of sequence identification number 4 would be associated or linked to Type II diabetes.

There are no disclosure or working examples that demonstrate the specifically asserted utility or evidences supporting a substantial utility that was well established at the time of filing.

The specification does not enable one of ordinary skill in the art to definitively assess the incidence of the disease in the tested samples. Furthermore, Applicants have not provided any disclosure enabling the use of the biopolymer marker with regard to regulating the differentiation (presence or absence) of said sequence. The disclosure is equally lacking any teaching for how the identified sequence will be utilized to identify therapeutic avenues and regulate a disease state.

Accordingly, the specification does not identify a substantial, credible or a well-established utility for SEQ ID NO:4. There is no disclosure designating how the sequence bound in these methods could be regarded as enabling one of ordinary skill in the art to use SEQ ID NO:4 as a marker.

Applicants have not set forth any supporting evidence that suggests that SEQ ID NO:4 is predictive of or associated with type II diabetes. Based on the analysis set forth above the specification does not exemplify sufficient findings that constitute a substantial, credible or well-established utility.

Art Unit: 1641

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a substantial, credible or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

Applicant respectfully disagrees with the Examiners interpretation of the data. Specifically, applicant contends that figure 1 contains samples from normal and Type II diabetes samples and compliments fragments were identified in Band 3 of lane 2 (Type II diabetes). However, when the data is reviewed as a whole it is deemed inconclusive because Band 3 is expressed in all the lanes (Type II diabetes as well as normal). Therefore, the use of the fragments of Band 3 as markers differentiating between normal and Type II diabetes would require further research to identify or reasonably confirm their use as substantial because conflicting results are presented in the specification.

Applicant also contends that lane 10 of figure 4 contains samples from normal and Type II diabetes patients that were differentially identified via complement fragments in Band 2 from lane 10. This argument was carefully considered but not found persuasive because Band 2 is identified or expressed in all the lanes (1-10) from various sample types (normal and Type II diabetes) figure 4 and no clear differentiation is identified in the disclosure.

Art Unit: 1641

Applicant argues that Band 3 is only labeled in lane 2 (diabetes Type II sample). This argument was carefully considered but not found persuasive because Band 3 appears in all the lanes (even though it is not labeled) and no clear differentiation between normal patient samples and diabetes Type II patient samples is evident. All the lanes have markings (band) in the same comparative area, they are not identified as different protein bands, therefor absent evidence to the contrary, they all appear to express Band 3. Patentability cannot be predicated upon an advantage that has not been expressly or at least implicitly; disclosed in the application as filed. *Clinical Products v. Brenner*, 255 F.Supp. 131, 149 USPQ 475, 480 (DDC 1966). Applicant is invited to show support in the disclosure for differentiation between normal Bands and Type II diabetes sample Bands.

Applicant argues that claim 1 has both a specific and a well-established utility because the specification discloses that sequences consisting of SEQ ID NO:4 are differentially expressed between Type II diabetes and normal samples and this sets for a link/association (not marker) between the sequences and Type II diabetes. This argument was carefully considered but not found persuasive because the specification teaches inconclusive data with respect to the expression of SEQ ID NO:4 in Type II diabetes. Accordingly a link or association between the claimed sequence and Type II diabetes is not exemplified in the disclosure.

Applicant contends that the invention has "real world" value. This argument was carefully considered but not found persuasive because utilities that require or constitute carry out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. Thus the utility requirement has not been meet.

Art Unit: 1641

Applicant also contends that the use of SEQ ID NO:4 is well established because a correlation between apolipoprotein A-IV and Type II diabetes is known (Verges et al., reference 4). However, the elevation of full-length apolipoprotein A-IV does not provide evidence that fragments consisting of SEQ ID NO:4 would also be elevated in Type II diabetes.

Applicant further contends that apolipoprotein A-IV fragment elevation or association with Type II diabetes would be a reasonable hypothesis. This argument was carefully considered but not found persuasive because the evidence of record is not substantial (convincingly presented in the specification) or well established (convincingly presented in the prior art). Therefore it would be reasonable to conclude that the utility would not be credible or well established based on the evidence of record. The rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit: 1641

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

Claim 1 is directed to a biopolymers consisting of SEQ ID NO:4. While the specification contends that the inventive sequences are diagnostic for/predictive of/linked to/associated with Type II diabetes. However, the specification does not support this assertion. The specification (in particular page 46) and figure 1 do not definitively correlate the absence/presence/differential expression of the claimed markers consisting of SEQ ID NO:4 to Type II diabetes.

Specifically, the specification recites that the biopolymers consisting of SEQ ID NO:4 are differentially expressed in the serum of normal patients when compared to patients suffering from Type II diabetes on page 46. However the disclosure does not contain any data supporting this contention and the figure 1 does not exemplify SEQ ID NO:4 (Only Bands are identified). Therefore it is unclear how SEQ ID NO:4 is identified as a “notable sequences” or how they were deemed “evidentiary” of a disease state (Type II diabetes).

Art Unit: 1641

Furthermore, Applicants have not provided any disclosure enabling the use of the biopolymer marker with regard to regulating the differentiation (presence or absence) of said sequence. The disclosure is equally lacking any teaching for how the identified sequence (SEQ ID NO:4) will be utilized to identify therapeutic avenues and regulate a disease state. There is no disclosure designating how the sequence could be utilized therein, enabling one of ordinary skill in the art to use the sequences in the diagnostic method.

Applicants have not set forth any supporting evidence that suggests that SEQ ID NO:4 is associated with Type II diabetes or any other disease and the prior art teaches that disease markers are highly unpredictable and require extensive experimentation.

Tascilar et al. (Annals of Oncology 10,Suppl. 4:S107-S110, 1999) reports on diagnostic methods in the realm of disease states, however this review article is relevant to Applicants' claimed invention. It is art known that molecular-based assays are valid tools used in predicting and detecting diseases, however as assessed in the Tascilar review "...these tests should be interpreted with caution..." and "the genetic changes found in sources other than the pancreas itself (blood, stool) should be evaluated prudently".

Furthermore, Tockman et al. (Cancer Research 52:2711s-2718s, 1992) teach considerations necessary for a suspected cancer biomarker (intermediate end point marker) to have efficacy and success in a clinical application. Although the reference is drawn to biomarkers for early lung cancer detection, the basic principles taught are clearly applicable to other oncogenic disorders.

Art Unit: 1641

Tockman teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials, see abstract. Early stage markers of carcinogenesis have clear biological plausibility as markers of preclinical cancer and **if validated** (emphasis added) can be used for population screening (p. 2713s, column 1).

The reference further teaches that once selected, the sensitivity and specificity of the biomarker must be validated to a known (histology/cytology-confirmed) cancer outcome. The essential element of the validation of an early detection marker is the ability to test the marker on clinical material obtained from subjects monitored in advance of clinical cancer and *link* those marker results with subsequent histological confirmation of disease.

“This irrefutable link between antecedent marker and subsequent acknowledged disease is the essence of a valid intermediate end point [marker]”, see page 2714s, column 1, Biomarker Validation against Acknowledged Disease End Points section. Clearly, prior to the successful application of newly described markers, markers must be validated against acknowledged disease end points and the marker predictive value must be confirmed in prospective population trials, see page 2716s, column 2, Summary section. Tockman reiterates that the predictability of the art in regards to cancer prognosis and the estimation of life expectancies within a population with a disease or disorder are highly speculative and unpredictable.

The instant disclosure has not addressed the issues taught in the prior art as crucial to the discovery of a biopolymer marker.

The nature of the invention- the invention is directed to disease markers or biopolymers.

Art Unit: 1641

The state of the prior art- the prior art of record fails to disclose the particular biopolymers in any disease state.

The predictability or lack thereof in the art- there is no predictability based on the instant specification that the biopolymers are indicative of any disease state including Type II diabetes.

The amount of direction or guidance present- appropriate guidance is not provided by the specification for the claimed biopolymers.

The presence or absence of working examples- working examples are not provided in the specification that exemplify the biopolymers as markers for any disease.

The quantity of experimentation necessary- it would require undue amount of experimentation for the skilled artisan to make and use the biopolymers as claimed.

The relative skill of those in the art- the level of skill in the art is high.

The breadth of the claims- as recited, the instant claims are directed to a biopolymer consisting of SEQ ID NO:4. The disclosure teaches that the claimed sequences are associated with Type II diabetes.

While it is not necessary to show working examples for every possible embodiment, there should be sufficient teachings in the specification that would suggest to the skilled artisan that the breadth of the claimed biopolymer is enabled. This is not the case in the instant specification.

. In view of the teachings of *In re Wands*, 8 USPQ2d 1400, it has been determined that the level of experimentation required to enable the breadth of the claims is undue.

Art Unit: 1641

Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may not be workable. See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966).

Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims and to practice the invention as claimed.

Response to Arguments

Applicant contends that because the disclosure identifies a *specific* use for sequences consisting of SEQ ID NO:4 the requirement of 35 USC 101 and 35 USC 112, first paragraph should be withdrawn. This argument was carefully considered but not found persuasive because 35 USC 101 not only considered a specific use but the use must also be found substantial, creatable and/or well established. Although applicant specifically recites that SEQ ID NO:4 is associated with Type II diabetes because it is differentially expressed in normal and patient sample, the specification and figures do not provide convincing data in this regard (not substantial or credible). The prior art does not teach SEQ ID NO:4, thus its use is not well established. This argument has been addressed a priori and the rejections are herein maintained.

Applicant argues that the evidence of enablement need not be conclusive but merely convincing to one of skill in the art and the instant specification provides sufficient evidence to convince one of skill in the art that the claimed peptides (SEQ ID NO:4) are linked and/or associated with Type II diabetes.

Art Unit: 1641

This argument was carefully considered but not found persuasive because the specification must teach how to make and use the invention, not teach how to figure out for oneself how to make and use the invention. In re Gardner, 166 USPQ 138 (CCPA 1970).

Although the instant specification discloses that SEQ ID NO:4 is associated with Type II diabetes on pages 46 and 47. The figures do not exemplify SEQ ID NO:4 as a differential indicator of Type II diabetes when compared to normal patients.

Specifically, applicant contends that figure 1 contains samples from normal and Type II diabetes samples and compliments fragments were identified in Band 3 of lane 2 (diabetes Type II). However, when the data is reviewed as a whole it is deemed inconclusive because the Band 3 appears in all the lanes (Type II diabetes as well as normal).

Therefore, the use of the fragments of Band 3 as markers differentiating between normal and Type II diabetes would require further research to identify or reasonably confirm their use as substantial because conflicting results are presented. No clear differentiation is identified in the disclosure. Patentability cannot be predicated upon an advantage that has not been expressly or at least implicitly; disclosed in the application as filed. *Clinical Products v. Brenner*, 255 F.Supp. 131, 149 USPQ 475, 480 (DDC 1966). Applicant is invited to show support in the disclosure for differentiation between normal Bands and Type II diabetes sample Bands.

Applicant contends that protein identification procedures are well known in the art (citing the disclosure and Patterson, 2000 reference 6). Applicant further contends that the differential-expression of protein markers in diseases is well known (citing Weinberger). Examiner does not disagree with these arguments.

Art Unit: 1641

However, the issue is not whether the protein sequences can be identified but if they are differentially expressed allowing for clear association with Type II diabetes and selection for protein identification. The specification has not disclosed this differential expression.

Applicant argues that the examiner addresses several issues relating to use of the claimed sequences and that these uses are not claimed. Further, applicant argues that enablement must be considered within the scope of the claims as indicated in MPEP 2164.08. This argument was carefully considered but not found persuasive because the claims were given their broadest reasonable interpretation that is consistent with the specification and in order for product claims such as claim 1 to be enabled the disclosure must present at least one enabled method of making and at least one enabled method of using the claimed product.

Applicant also contends that the use of SEQ ID NO:4 is well established because a correlation between apolipoprotein A-IV plasma levels and Type II diabetes is known (Verges et al., references 3 and 4). However, the elevation of full-length apolipoprotein A-IV does not provide evidence that fragments consisting of SEQ ID NO:4 would also be elevated in Type II diabetes.

Applicant argues that the specification discloses sequences consisting of SEQ ID NO:4, which are differentially expressed between Type II diabetes and normal samples, and this provides a link/association (not marker) between the sequence and Type II diabetes. This argument was carefully considered but not found persuasive because the specification teaches inconclusive data with respect to the expression of SEQ ID NO:4 in Type II diabetes. Accordingly a link or association between the claimed sequence and Type II diabetes is not exemplified in the disclosure.

Art Unit: 1641

Applicant contends that the references of Tascilar et al. and Tockman et al. were not relevant to the instant invention because they do not teach SEQ ID NO:4 and its association to Type II diabetes. This argument was carefully considered but not found persuasive because the references were merely cited to show the state of the art with respect to marker discovery. A rejection is proper though a reference is not prior art when it establishes the level of ordinary skill in the art at the time of the claimed invention. Ex parte Erlich, 22 USPQ 2d 1463, 1465 (Bd.Pat.App,1992).

The enablement issue is whether one skilled in the art could have made or used the sequence consisting of SEQ ID NO:4 as a link or in association with Type II diabetes without undue experiment at the time the application was filed. The specification and the prior art have not clearly set forth a link between the claimed sequences and Type II diabetes, therefore it is deemed that undue experimentation is required to use the sequence. Accordingly, the rejection is maintained.

12. For reasons aforementioned, no claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action.

Art Unit: 1641

In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

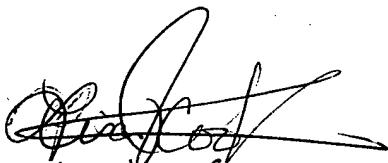
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

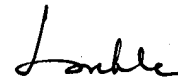
Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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07/22/05